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510(k) SUMMARY AS REQUIRED BY SECTION 807.92(C)

Submitted by: Mrs. Mitsuko Yoneyama
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Date Submitted: October 18, 2000

Device Identification:

Trade Name:	MO-202D Three-axis Hanging Joystick Oil Hydraulic Micromanipulator
Common Name:	Fine Micromanipulator
Classification Name:	Assisted Reproduction Micromanipulators and Microinjectors (21 CFR, 884.6150)

Predicate Device:

The MO-202D Three-axis Hanging Joystick Oil Hydraulic Micromanipulator is substantially equivalent to predicate 3D Hydraulic Fine Micromanipulator MO-188NE.

Device Description:

The MO-202D Three-axis Hanging Joystick Oil Hydraulic Micromanipulator helps fine positioning of a microtool under the microscope.

The MO-202D is an oil hydraulic fine micromanipulator and consists of two parts: the Control Unit and the Drive Unit. They are connected with the 800-millimeter long oil hydraulic tubing (Teflon tube). This product is controlled by the built in oil hydraulic system and does not require any external power input.

The Drive Unit consists of three sliders, the X-axis Unit, Y-axis Unit, and Z-axis Unit, and all of which move to the different direction:
- X-axis for X-axis Unit (right-left with relation to the microscope);
- Y-axis for Y-axis Unit (front-back with relation to the microscope);
and Z-axis for Z-axis Unit (up-down with relation to the microscope).

The Control Unit has control knobs for X-, Y-, and Z-axis and connected with the oil hydraulic tubing to the X-axis Unit, Y-axis Unit, and Z-axis Unit, respectively, of the Drive Unit. Turning the respective control knob controls each axis. The maximum movement range is 10mm for each axis.

There is also the Joystick on the Control Unit, and it controls the X-and Y-axis Unit simultaneously allowing maximum operating area of a 2mm-diameter circle.

The MO-202D Three-axis Hanging Joystick Oil Hydraulic Micromanipulator is a component part of a micromanipulator system.

A micromanipulator system for ICSI, requires:
- 1 unit of manipulator mounting adaptor;
- 2 units of coarse manipulator (for coarse positioning);
- **2 units of fine micromanipulator (for fine positioning) (2 units of the MO-202D);**
- **2 units of the Universal Joint (for holding the pipette holder);**
- 2 units of microinjector (one for holding pipette and one for injecting pipette);
- 1 holding pipette
- 1 injecting pipette

Examples of role the MO-202D plays in the ICSI would be:
- fine positioning of the holding pipette close to the oocyte.
- fine positioning of the injecting pipette close to the sperm.
- inserting the injecting pipette, equipped with the sperm into the oocyte.

Intended Use:

The MO-202D Three-axis Hanging Joystick Oil Hydraulic Micromanipulator helps fine positioning of a microtool under the microscope and is used in assisted reproduction procedures.

Substantial Equivalence:

Narishige Co., Inc. claims MO-202D Three-axis Hanging Joystick Oil Hydraulic Micromanipulator as substantially equivalent to 3D Hydraulic Fine Micromanipulator MO-188NE, Premarket Notification 510(k) Number: K001131.

Technological Characteristic:

The MO-202D Three-axis Hanging Joystick Oil Hydraulic Micromanipulator is an oil hydraulic fine micromanipulator which gives positive smooth movement. It can be converted from the right-hand use to the left-hand use or vice versa simply by rearranging the Drive Unit and the Control Unit. It may be set up for either right- or left-handed use. The Drive Unit and the Control Unit are connected with the 800-millimeter long oil hydraulic tubing so that only the Drive Unit is mounted to the microscope leaving the Control Unit independent of the microscope. Therefore, the Control Unit does not transfer the vibration through the tubing, the

Drive unit, linkage, and to the microtool when controlling the Control Unit. This enables the stable operation.

The Drive Unit is designed compact allowing ample space around the microscope stage.

The Control Unit is designed for one hand easy operation. Each Control Knob is located close together, the X- and Y-axis Control Knobs located by the Joystick and the Z-axis Control Knob located at the bottom of the Joystick, and within reach without much moving the hand.

The Joystick allows the movement of the microtool exactly the same way as the hand.

The movement range of each control is summarized in the table below.

Control Unit	**Drive Unit**
X-axis Control Knob:	**X-axis Unit:**
Minimum Graduation	5μm
One Rotation of the Control Knob	500μm
Maximum Movement Range	10mm
Y-axis Control Knob:	**Y-axis Unit:**
Minimum Graduation	5μm
One Rotation of the Control Knob	500μm
Maximum Movement Range	10mm
Z-axis Control Knob:	**Z-axis Unit:**
Minimum Graduation	5μm
One Rotation of the Control Knob	500μm
Maximum Movement Range	10mm
Joystick	Simultaneous movement of the X-axis Unit and Y-axis Unit, allowing maximum operating area of a 2mm-diameter circle.

Quality Assurance Steps

The inspection of the precision and accuracy of range and of movement of the MO-202D Three-axis Hanging Joystick Oil Hydraulic Micromanipulator is carried out under the microscope.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 22 2000

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JAPAN

Re: K003300
MO-202D Three-axis Hanging Joystick Oil Hydraulis Micromanipulator
Dated: October 18, 2000
Received: October 20, 2000
Regulatory Class: II
21 CFR §884.6150/Procode: 85 MQJ

Dear Ms. Yoneyama:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K003300

Device Name: **MO-202D Three-axis Hanging Joystick Oil Hydraulic Micromanipulator**

Indications For Use:

The MO-202D Three-axis Hanging Joystick Oil Hydraulic Micromanipulator helps fine positioning of a microtool under the microscope and is used in assisted reproduction procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

David A. Lyerm

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K003300

Prescription Use ✓
(Per 21 CFR 801.109)